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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,152	02/08/2001	Leigh T Canham	124-821	3931

7590

12/18/2002

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EXAMINER

PEREZ RAMOS, VANESSA

ART UNIT

PAPER NUMBER

1765

7

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/744,152

Applicant(s)

CANHAM ET AL.

Examiner

Vanessa Perez-Ramos

Art Unit

1765

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

Art Unit: 1765

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-35, drawn to a method of providing a silicon micro needle, classified in class 438, subclass 689.
  - II. Claim 36, drawn to a silicon micro needle, classified in class 257 subclass 40.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make another materially different product, such as a micro needle made of a material different than silicon, or made of several materials.
3. During a telephone conversation with Stanley Spooner on December 4, 2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-35. Affirmation of this election must be made by applicant in replying to this Office action. Claim 36 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1765

5. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 recites the limitation "a method according to claim 25...wherein the porosification...". There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ginavan et al (U.S. 5,457,041).

8. In regard to claims 1-15, Ginavan discloses a method for providing a silicon micro needle (col. 8, lines 52-62), the micro needle having a base adjoining a substrate (See Fig. 1, where "16" is the substrate and "12" is the micro needle, which adjoins the substrate through its "base" or lower portion; see also col. 7, lines 3-7); a tip remote from the base (col. 7, line 14 and also Fig. 1, where it is shown that needle tips "28" are on the opposite side of the base, or "remote from said base"); and a region between the tip and the base (see Fig. 1, the region between tip "28" and the base adjoining substrate "16"; see also col. 7, lines 55-67), which reads on Applicant's "duct", and "wherein the duct passes substantially between the tip and the base"; and wherein the method comprises providing said duct (col. 7, lines 55-67 and Fig. 1) and selectively removing the substrate from around the duct to provide the micro needles

Art Unit: 1765

"coincident" with the duct (col. 8, lines 59-67 and col. 9, lines 1-29). Furthermore, Ginavan discloses the use of a mask (col. 9, lines 14-29), the use of plasma etching, anisotropic etching, etching with a resist mask and several other etching procedures for the removal of material (col. 9, lines 55-65).

In regard to claim 16, it is noted that Figs. 1-5 show that the walls of micro needle "12" can be flat, pointed, jagged, concave or hollow (see also col. 7, lines 53-65) and it is believed that some of these different shapes read on Applicant's limitation that the micro needles are "inclined to a plane that is perpendicular to the substrate".

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 17-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginavan (U.S. 5,457,041) as applied to claims 1-16 above, and further in view of Busta et al. (U.S. 5,137,817).

In regard to claims 17-35, these claims differ from claims 1-16 above by adding the limitation that the base of the micro needle adjoins a first material, while the duct is lined with a second material, thereby forming a two-material micro needle.

Ginavan does not disclose a two-material micro needle as the claimed invention does.

Busta discloses the formation of what he calls "electrodes" which read on Applicant's "micro needles", and discloses that they adjoin a first material, are lined by a second material

Art Unit: 1765

and are thereby formed of the two materials (col. 10, lines 51-68 and col. 11, lines 1-62). Busta teaches that the use of two materials for the micro needle allow for lower voltage requirements, easier access to their targets and rapid treatment times (col. 4, lines 20-44). Furthermore, Busta discloses that the duct of the electrode or micro needle is linked to a reservoir (col. 11, lines 5-10 and 25-31).

It is the Examiner's position that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ginavan by utilizing two materials for the formation of the micro needles, as per Busta, because this is a well known procedure in the art and, furthermore, because this modification could result in lower voltage requirements, easier access to their targets and rapid treatment times, which is extremely desirable.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa Perez-Ramos whose telephone number is 703-306-5510. The examiner can normally be reached on Mon-Thurs 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Benjamin Utech can be reached on 703-308-3836. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-5665.

Vanessa Perez-Ramos  
Examiner  
Art Unit 1765

VPR  
December 12, 2002

  
**BENJAMIN L. UTECH**  
SUPERVISORY PATENT EXAMINER  
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